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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,615	02/04/1999	JAMES P. HOEFFLER	INVIT1100-1	5087

7590 10/13/2004

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/245,615	HOEFFLER ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-40 and 51-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-40 and 51-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed October 25, 2000 is acknowledged (fax receipt 4/26/04). In the amendment filed therein the specification was modified to include priority reference. Claims 1 to 30 and 41 to 50 were cancelled without prejudice (filed 7/26/00). Currently, claims 31 to 40 and 51 to 59 are pending and under consideration.

Remarks

2. Objections and/or Rejections of record not reiterated below have been withdrawn.

OBJECTION WITHDRAWN

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form PTO-1449 has cited the references they have not been considered.

4. The information disclosure statements filed 01 June 1999, filed 12 October 1999, filed 26 November 1999, and filed 27 June 2000 have been considered as to the merits before Final Action.

5. The information disclosure statements filed 18 June 2001 and filed 07 May 2004 have been considered as to the merits before Final Action.

OBJECTION MAINTAINED

Drawings

6. The drawings in this application are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the examiner allows the application.

Applicant has requested deference of the cited drawing corrections until allowance. The objection is maintained until the drawings are corrected.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 31-40 and 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "uncharacterized" in claim 31 is a relative term which renders the claim indefinite. The term "uncharacterized" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what applicant intends to encompass with respect to the antibodies.

Are uncharacterized antibodies directed to any known antibody or unknown antibodies? Are "uncharacterized antibodies" defining the binding ability of the antibody? For example it is not known what antigen binds the antibodies? Or does "uncharacterized" mean the antibodies are to meet some other parameter not clearly identified. It is suggested that the term be removed or defined such that the intended meaning is clear. Please clarify.

B. Claims 31, 32, 36, 37, and 38 are vague and indefinite because the recite "instruction for use" but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Further, the claims are not directed to a method, therefore the limitations regarding instructions for utility are not given patentable weight in the product claims to a kit (diagnostic pack). Appropriate correction is required.

C. Claim 51 is vague and indefinite in utilizing the phrase "source of" the antibody. Although the phrase has defined meaning it is not clearly defined in the method of the instant application. Is it applicants' intent to mean that the antibody is known to occupy a specific position or is this limitation directed to the origination of the antibody (antibody derivation). It is suggested that the claim clarify Applicants intent. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 31-32, 36-38, 53, 54, 57, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirschfeld (US Patent #4,514,508).

Hirschfeld disclosed kits (diagnostic packs) with antibodies immobilized on solid phase surfaces, such as microtiter plates (reading on array). Column 5 lines 3-18. Antibodies against specific antigen or haptens (characterized) are applied to a solid phase matrix at different positions. A non specific coating is also added to the solid phase matrix (claim 58). Column 4 lines 12-45. The kit also contains detecting compounds and buffers (reagents for detecting the antigen). In one embodiment a 96 well microtiter well is employed. See Example 1, column 5 line 40, for example.

With respect to the antibodies being "uncharacterized", it is noted that the cited art teaches the immobilization of a plurality (various IgG preparations) of any antibody and therefore inherently reads on characterized and uncharacterized antibodies. See column 4 lines 14-18 and example 3, in particular lines 19-24.

Although the reference does not specifically disclose that the diagnostic pack or kit would have instructions which teach how to use said kit, instructions are not given patentable weight in kit claims. Applicants should note that the printed matter on the instructions in a kit cannot serve to define the kit over the prior art. See in re Gulack 217 USPQ (CAFC 1983).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 33-35, 39-40, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschfeld (US Patent #4,514,508) in view of Ragg and Whitlow (FASEB, Vol.9, January 1995, pages 73-80).

Please see previous discussion of Hirschfeld (US Patent #4,514,508) as set forth above.

Hirschfeld (US Patent #4,514,508) differs from the instant invention in not teaching antibody fragments such as single chain/stranded recombinant antibody compositions.

However, Raag and Whitlow disclose single chain recombinant antibody fragments (sFv) consisting of only the variable light chain (VL) and variable heavy chain (VH) domains covalently linked by a polypeptide linker. Because the single chain recombinant antibody fragments are small they have rapid pharmacokinetics and tumor penetration in vivo. See abstract. These single chain recombinant antibody fragments are derived from the antigen-binding domain of antibodies and are useful in any molecular recognition or binding application. See page 74 2nd column 2nd paragraph. SFv's are disclosed as time reducers in ELISA application. See page 74 2nd column middle of the 3rd paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use antibody fragments like recombinant single chain/stranded antibodies (sFv) as taught by Raag and Whitlow in the kit and method of Hirschfeld (US Patent #4,514,508) to perform multiple sample analysis in the rapid detection kits systems because Raag and Whitlow taught that sFv's were small allowing for rapid penetration (abstract), useful in any antibody application (page 74 2nd column 2nd paragraph), and reduced time in ELISA procedures page 74 2nd column middle of the 3rd paragraph.

III. Claims 51-52 and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschfeld (US Patent #4,514,508) in view of Heller et al. (U.S.Patent#5,605,662).

Hirschfeld (US Patent #4,514,508) are set forth above.

Hirschfeld (US Patent #4,514,508) differs from the instant invention in not specifically teaching antibody compositions at known spatially addressable locations on the array or 96 well microtiter plate.

Heller et al. disclose a microelectronic device designed and fabricated to carry out molecular biological reactions in a microscopic format. In one embodiment addressable micro-locations (applicants discrete locations) are positioned on a substrate (applicants solid surface). See for example, figures 8[a-d] and 9[a-c]. The reactions include molecular biological procedures, such as nucleic acid hybridization, antibody/antigen reaction, and related clinical diagnostics. In addition the device is employed in biopolymer synthesis. In general the device has large micro-locations (>100 microns) and can be fabricated in three-dimensional formats (e.g. tubes or cylinders) in order to carry a large amount of the binding entities. The device is has utility in a variety of materials, including plastic, rubber, silicon, glass or ceramics (Column 14, Lines 25-41). Discrete locations are treated to minimize non-specific binding on the solid support. See column 10 lines 33-40, wherein chemical techniques are utilized to concentrate and covalently attach specific binding entities to the specially modified surfaces.

A specific example of a 96 microlocation device is illustrated in Fig. 5 of this invention. The micro-location device is fabricated from a suitable material stock and 96 proportionately spaced holes are drilled through the material. An electrode circuit board is formed on a thin sheet of plastic, which fits precisely over the top of the micro-location component.
The underside of the circuit board contains the individual wires to each micro-location. Each micro-location has an individual buffer reservoir, which separates adjacent surfaces. The wiring is coated with a suitable water-proof insulating material.

The device is partially immersed and operates in a common buffer reservoir, applicants interconnected sumps for drainage. (Column 14, Lines 41-60). The device of Heller et al. having self-addressed specific binding entities can be utilized in several reactions and analyses. The device leads to significant improvements in reaction rates, specificities, and sensitivity. Column 16 lines 24-46.

Applicant contends that Heller et al. describe methods of producing "specially designed addressable microscopic locations". Therein reading on spatially addressable. Response filed 26 April 2004 on page 4-5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use antibody compositions at known spatially addressable locations on the array or 96 well microtiter plate as taught by Heller et al. in the kit/method of Hirschfeld (US Patent #4,514,508) to perform multiple sample analysis in the rapid detection kits systems because Heller et al. taught that this antibody location configuration could be utilized in several reactions and analyses. The device leads to significant improvements in reaction rates, specificities, and sensitivity. Column 16 lines 24-46. Further, knowing the location of each antibody on the solid phase allows for specific detection and evaluation of each antibody and its interaction with the antigen.

Response to Argument

Applicant's arguments with respect to claims 31 to 40 and 51 to 59 have been considered but are moot in view of the new ground(s) of rejection.

10. For reasons aforementioned, no claims are allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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